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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,453	10/07/2003	Randal A. Stevens	34597.1	4505

32300 7590 12/29/2006

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EXAMINER	
PADGETT, MARIANNE L	
ART UNIT	**PAPER NUMBER**
1762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/680,453	STEVENS ET AL.	
	Examiner	Art Unit	
	Marianne L. Padgett	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/11/2006 has been entered.

Compliance problems in the 9/11/2006 amendment indicated on the PTOL-324 mailed 9/28/2006, have been corrected by the submission of 10/26/2006, however one noted potential oversight that is not a compliance problem *per se* remains and has created new matter problems.

2. Claims 1-2, 4-9 & 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In independent claims 1 & 6, the steps now labeled (e) or (f), respectively, still referred to the removing of excess UV curable substance with respect to steps (c) or (d), but the steps those labels refer to has now been changed such that it refers to the step where draining of UV curable substance is performed. This is not supported by the original specification, since while the original claim 1 does not necessitate an order in which steps were performed, the listing implies an order, especially read in light of the original specification which in the detailed description (page 4, in combination with the flowchart of figure 1 & Experiment 1 on page 5, clearly requires the removing step (which is not a draining step) such as in an ultrasonic alcohol bath, to be done after a UV curing step has been performed on the uncured layer. To require a removing step other than the draining step to be performed before curing, especially if it is using alcohol and optionally also ultrasonic, is not supported by the original specification (nor probably intended, as it appears that it would effectively remove all of the uncured [polymeric] substance), effectively not leaving anything left to coat the outer surface of the hearing aid shell. This

would also effectively create an enablement problem, in that it is unclear how one is able to have anything left to cure after using techniques such as an alcohol bath on a layer of completely uncured material.

3. Claims 1-2 & 4-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the independent claims, the amendments to the coating & draining steps have made the relationship between the differently labeled layer of each step uncertain, noting that the situation also affects the step of removing excess substance. Referring to independent claim 1 with the others containing analogous language, step (b) created "a new layer of UV curable substance", while steps (c) requires "leaving in uncured layer", however there is no requirement that there is any connection between the substances of these two differently labeled layers (also a potential new matter problem, in that the specification does not teach such an option), leaving the meaning uncertain or ambiguous, since while the only apparent source of the uncured layer is from the preceding coating step, it is not necessitated, especially in light of the removing steps in all the independent claims, where claims 1 & 6 now directly referrer to the draining step, hence effectively may remove all the applied substance, or in claim 10 where the removing step can be done at any time during the process after application of photocurable polymer, since order of listing does not necessitate order of doing a step, unless explicit language of the claims require in order (temporal language or antecedent basis).

Using claim 1 as an example, would the phrasing --an uncured residual layer of UV curable substance-- in place of "an uncured layer" in step (c), which the examiner considers consistent with the original specification & considers to correct the above problem, provide applicants' intent? It would also help clarity/flow in the claims to insert -- thus -- before "creating" in step (b). Also correction of the removing steps would be desirable, to refer to the exposing step in claims 1 & 6, with claim 10 being

clarified either by reference to the preceding step (e) or by inserting --after the exposing-- or the like, such that step 10(f) is not merely a rephrasing of the draining that occurs in step (d).

4. Claims 1-2 & 4-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement was not found in the specification for removing excess UV curable substance/polymer by any technique except for draining, before UV exposing was performed, however all the independent claims potentially or ambiguously require (claims 1 & 6) or include the option (claim 10) of some sort of removing, that in the dependent claims includes an alcohol bath, optionally using ultrasound, before any UV curing/exposing occurs. The specification does not provide enablement for such a procedure, as it is unclear what would be left as a coating and requiring curing after employing such a vigorous removal techniques. Also see about discussions.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-2 & 4-13 are rejected (claims 4-5 & 8-9 tentatively) under 35 U.S.C. 103(a) as being unpatentable over Hanna (6,660,208 B2 = 2004/0028253 A1 = EP 124536982), in view of Farnworth et al (6,482,576 B1) as set forth in sections 4 of the actions mailed 12/8/2005 & 6/30/2006.

Note the claims 4-5 & 8-9 are only tentatively include that in this rejection due to the above discussed clarity/new matter problems since the combination of references does not coat with a curable material, then remove it all in an alcohol bath and cure something that does no longer exist, as is essentially presently claimed. However since the examiner doubts it applicant actually intended this, these claims are tentatively included here considering the probable intent as per previous claims and the original specification.

Applicants have also amended the claims to require the initial step of the shell being created by stereolithographically processes, then coating the ear shell to create a new layer, however all the applied references create the body of their product via stereolithographically techniques as previously discussed, and it is further noted that Farnworth et al. who teaches a specific process for improving the overall surfaces of a body made by stereolithographic techniques, does so by lifting the multilayered structure out of the photopolymer bath, which process is equivalent of applicant's claim of creating a new layer. Farnworth et al. as previously noted then proceeds to drain excess liquid therefrom, which is the equivalent of applicants' step "to drain off... leaving an uncured layer", hence these amendments to the claims are not considered to provide any unobvious step that may produce any unexpected results to the process, especially as Farnworth et al.'s technique is taught to be generally applicable to the fabrication of stand-alone structures (col. 4, lines 19-23 & col. 14, lines 39-49) and Hanna particulate notes the conventionality of coating hearing aid shell bodies, such that Farnworth et al. provides an efficient means of effecting this conventional known procedure while providing advantages as taught therein. As previously discussed, as this surface overcoating suggested by this combination of references is also UV cured & of the same UV curable material as employed in constructing the body, it would have required

the alcohol extraction technique of Hanna et al., where it would have been obvious to one of ordinary skill in the art that is employing Farnworth et al. smoothing technique to coat the stereolithographically object, that one would employ the extraction/detoxification technique with alcohol, etc., after this overall surface coating technique, as that would be the only logical and effective way to proceed, and would be in keeping with Farnworth et al.'s teachings concerning reducing quantity of polymers consumed in combination with production of smooth walls (col. 14, lines 50-57).

To reiterate, Hanna teaches making hearing aid shells via stereolithographic techniques, where in order to produce biocompatible products, it is necessary to detoxify by extracting cytotoxins remaining from the stereolithographic polymerization procedures, which may involve UV curing. Several different means of doing so are taught, which are inclusive of extracting with alcohols, such as isopropyl alcohol alone, or with use of such alcohols in ultrasonic bath, with teachings on sufficient times for these procedures to extract unpolymerized residues from the stereolithographically constructed hearing aid shells, which affects required detoxification. Thereafter, post UV curing finishes the cure of the produced shell, and it is further taught that it is common practice to further coat hearing aid shells, such as with UV curable lacquer. In Hanna (EP), see the abstract; figures 2-3 & 7; [0001]; [0005]; [0009-10]; [0012]; [0014-15]; [0022-23]; [0030-33]; especially [0039]; and [0042-49].

While Hanna uses an analogous series of steps to applicants' procedure of UV polymerization and extraction/removing for constructing the hearing aid shell, they differ by not giving any similar details for their generically disclosed UV curable coating of that shell. However, Farnworth et al. teach a procedure for coating stereolithographic structures, where they teach their process is applicable to any structure made by stereolithography, which is advantageous for smoothing the surface to get rid of crevices at the layer interfaces on the surface, which are undesirable as they may be unsightly and they may collect dust, dirt and moisture. When Farnworth et al. lift the structure in its final form from the stereolithographic polymer bath, instead of washing any unpolymerized resin from the crevices, they merely drain the excess

polymer from the structure so as to leave a coating that fills the crevices, reading on applicants' "uncured layer", then they cure by either UV laser or broad beam or flood type UV radiation, after which typical final curing procedures, including washing with alcohol and UV post curing may be performed. In Farnworth et al., see the abstract; figures 1 & 6-10; col. 1, line 7-18; col. 2, lines 13-25 & 61-67; col. 3, line 41-col. 4, line 23; col. 5, line 52-col. 6, line 17; col. 8, line 49-col. 9, line 5+; col. 11, line 35-col. 14, line 68, especially col. 12, lines 1-40 & 58-67, col. 13, lines 5-35 & 48-col. 14, lines 13 & 39-57.

It would have been obvious to one of ordinary skill in the art to use the surface smoothing coating procedure of Farnworth et al. to produce the stereolithographic hearing aid shells of Hanna, in order to achieve the advantageously smooth surface as taught in Farnworth et al., as it provides a specific procedure for creating the suggested UV cured coating, and further provides the advantageous elimination of crevices that can collect dirt, as well as being economical in its use of photo polymeric resin, which is not wasted by washing away, and in consideration of how this coating procedure enhances wall uniformity, affecting the size of final object. It would have been further clear to one of ordinary skill in the art, that one would use the detoxification procedures (i.e. use of alcohol in ultrasonic bath or to chemically extract undesirable unpolymerized residues after the initial UV cure) of Hanna on the so produced coating of the stereolithographically produced hearing aid shell, in order to have a biocompatible product after final cure, as the reasons for performing the extraction (≡ removing excess) would have been equally applicable to the UV cured overcoating, as to the UV cured body of the shell.

With respect pre-sizing, as previously discussed and paraphrased, in any process that requires the article being made to have a precise size in the end product, i.e. with the tolerances for the size produced are extremely small, any competent technician, let alone designer, would have been expected to figure in the thickness of a coating being applied over the exterior of the item, when calculating the size of the substrate to be coated. It would have been a matter of basic complements to do so with the claimed "ear shell", as it is conventional in the art to make this individualized to the person, i.e. the tolerances for

what will fit in not fit our small. Claiming a limitation that would be done as a matter of course by any competent practitioner, cannot be considered to provide a patentable limitation to a process.

The examiner additionally notes that as both Farnworth et al. & Hanna are directed to stereolithographically processing of custom designed objects (Farnworth et al.-col. 2, lines 12-26 & 60-67+, especially 18-20 & 61-63; Hanna-(EP)-abstract, [0004], specifically directed to hearing aid shells), that there are essentially two ways to get that custom-designed shape/size correct, either make it to the correct dimensions the first time, or to machine it down to size afterwards. There would be no point in using the stereolithographic techniques of these references to build up a shape to a size that was not the desired size, inclusive of the coating applied to the layered object, as it is part of the layered object, i.e. just another layer, and any competent practitioner would readily realize that it had to be included in the design calculations for the overall shape & size, if one was not going to have to machine the shape down to the appropriate size after final layer deposition (& cure). As the primary reference to Hanna specifically teaches that one of the advantages of the stereolithographic process is to eliminate the need for machining ((EP)-end of [0004]; or in (208) col. 2, lines 1-26, especially 19-22) with specific teaching of the shell itself being coated with UV curable lacquer ((EP)-[0039]; or in (208)-col. 8, lines 55-60), any overcoating layer(s) would have been expected to be considered included when this customized object's required size was determined, including all layers deposited, both body and overcoating, otherwise one would be required to either machine the end product (which Hanna teaches against) or have a fatally defective product, i.e. one that does not can fit one's customer's ear or the like.

5. Applicant's arguments filed 10/26/2006 & 9/11/2006, and partially discussed above have been fully considered but they are not persuasive.

With respect to Hanna, applicant argues that Hanna is not using specific alcohols for specific time periods before "post-curing", by which they presumably mean the second curing/exposing step, however none of these parameters are claimed, hence are irrelevant to the arguments which required neither

specific alcohols nor specific parameters for the application of the bath. With respect to Farnworth et al., applicants' discussion with respect to not applying an additional UV coating does not make sense with respect to the claims as written, as steps (a) & (b) of claim 1 or analogous steps in the other independent claims, are performing a sequence of steps that encompasses a like sequence taught by Farnworth with respect to generic stereolithographic structure formation & a smoothing layer. Applicant's comments concerning Farnworth et al.'s additional tilting steps, are irrelevant, as neither applicants' claims nor specification excludes such actions for the manipulations applied in affecting the coating and draining processes.

Applicant's discussion of the two references Farnworth et al. and Hanna, essentially discusses each reference as a stand-alone reference, which they are not. Applicant merely careless with the combination by saying that it would not reasonably produce success, without dealing with the reasons why they are combined or the effects of the combination in a reasonable manner which would be applied by one of ordinary and competent skill in the art. Applicant appears to object to the examiner's characterization of a competent technician, let alone the designer, having been expected to figure in the surface coating thickness in calculating the size of the substrate which will be coated to form the final object, saying that the examiner has failed to identify what would be the ordinary skill of someone in the art. An ordinary technician (or engineer) who is making/designing a customized object as required by either of these references, who failed to "pre-sized" or measure their customers required dimensions & to use those previously obtained/calculated final dimensions (inclusive of all layers, stacked or overcoated, that form the final object) in performing an additive process (i.e. stereolithographic process), would likely be fired for incompetence, since as pointed out by the primary reference to Hanna, one of the points of using stereolithographic processing is to avoid or to eliminate the need for machining, which would necessitate taking into account ALL layers. Also see above art rejection, especially of beginning & ending paragraphs.

The examiner thanks the applicants for the quotation from "Landis..." (page 7 of 810/26/2006 response) whoever he/she/it is, as she was not aware that that such poor advice was being recommended to applicants, which can frequently result in effective broadening of (intended) scope, or indefinite or ambiguous claim language. The order of listing DOES NOT NECESSITATE any order of performing the steps, and no place in the MPEP that the examiner is aware of says that it does, in fact many applicants frequently intentionally claim steps that are not recited in the order in which they are done or are intended to include multiple orders, so the examiner cannot assume that steps that must necessarily follow (be done in) an order in which they are listed, especially when alternate orders, particularly for generically claimed actions, are not prohibited. The examiner is required to read the claims in their broadest reasonable possible meaning, hence if as in the case of applicant present claim 10, applicants writes their claims (intentionally) so as to include steps that may be refinements of previously listed steps or done in several different alternative orders, the examiner must consider all those possibilities to be included by the claimed language, which has been written to encompass all those possibilities. While the claims will generally encompass the steps being performed in the order they are listed, lacking limiting phrases/nomenclature, they will not exclude performance in alternate orders.

6. Other art that interest includes Widmer (7,014,010 B2; column 3-6, especially column 6, lines 19-40), Mullenborn et al. (7,142,682 B2; stereolithography -customization & avoids use of multiple techniques to form housing), & Feeley et al. (7,016,512 B2; column 20), who provide additional teachings on customizing hearing aid components via use of stereolithography. The publications to Haussmann (2006/0140430 A1) & Bachler et al. (2006/0233384 A1) are also of interest to the state of the art for stereolithographic formation of hearing aid components, but are not prior art.

Other art of interest have been previously noted to include Sauerhoefer (5482659) who teaches a stereolithographic process including post-processing steps of submerging in alcohol with ultrasonic agitation, drying & UV post-treatment curing. Johnson et al. (2005/0175925 A1) teach a specific

composition and structure of photocurable material for making three the objects with generally smooth surfaces when cured, which may be used for making housings for hearing aids (abstract & [0011], etc.).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MLP/dictation software

9/23/2006

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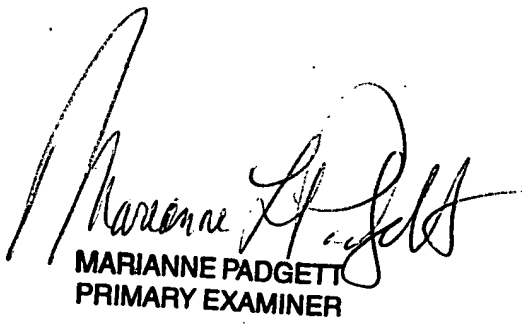

MARIANNE PADGETT
PRIMARY EXAMINER